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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/540,343	10/06/1995	DENNIS E. HALLAHAN	ARCD:194	8900

7590

05/05/2003

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/05/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/540,343

Applicant(s)

Hallahan et al.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 10, 11, 13, 15, 18-27, and 35-55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10, 11, 13, 15, 18-27, and 35-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

The request filed on 3/5/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/540,343 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 102 & 103

Claims 8, 10, 11, 13, 15, 18-27 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Martuza et al., US 5,585,096, filed 7/94 - hereafter Martuza A.

Claims 8, 10, 11, 13, 15, 18-27 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Martuza et al., US 5,728,379 (filed 6/1995 and claiming priority to US 5,585,096, filed 7/94) - hereafter Martuza B.

Claims 35-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick, US 5,846,945 (filed 6/1995, claiming priority to applications filed 2/1994 and 2/1993) in view of a) either Martuza A or Martuza B, or b) Frisch, US 5,776,743 (filed 9/1994); or c) Frisch and either Martuza A or Martuza B.

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Response to Arguments

Applicant's arguments filed 4/11/03 have been fully considered but they are not persuasive. The declaration filed on 4/11/03 under 37 CFR 1.131 has been considered but is ineffective to overcome either Martuza reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Martuza references. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The exhibit provided with the declaration shows conception of an invention by three of the five instant inventors comprising administering an HSV-1 mutant virus with a γ 34.5 deletion (it is unclear whether one of both copies of the γ 34.5 are deleted) directly into an unspecified human tumor followed at some unspecified time by irradiation of the tumor. It is presumed that this mutant HSV-1 is replication competent, at least in tumor cells.

However, this species, while embraced by that of instant claims 8, 10, 11, 13, 15, 18-27 is far narrower than that claimed. No claims are limited to the use of the specific HSV-1 of the exhibit or of a replication competent HSV-1, most claims are not limited to HSV-1, and many of the claims are not limited to treatment of human tumors. Consequently, the showing provided by the declaration is not commensurate in scope with the invention now being claimed. Applicant

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has provided no evidence that one of skill in the art at this time would have considered the activity disclosed by the exhibit as evidence of possession of the invention relating to HSV as broadly claimed. The exhibit provides no evidence of conception for the invention as directed to the use of adenovirus. The invention falls into the physiological art which has long been held to be unpredictable. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Martuza references to either a constructive reduction to practice or an actual reduction to practice. Although the exhibit indicates that some experimental activity had been conducted which supported the invention described in the exhibit, there is no indication as to what the activity was, i.e. whether it included an actual reduction to practice. No evidence has been provided showing diligence in developing the claimed invention from the time of exhibit to the time of an actual reduction to practice or constructive reduction to practice.

Conclusion

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

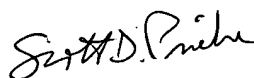
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER